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K000556

élan diagnostics

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SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS INFORMATION

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The ATAC PAK Glucose Reagent Kit, the ATAC Calibrator and the ATAC 8000 Random Access Chemistry System are intended for use as a system for the quantitative determination of glucose in serum, plasma, urine and cerebrospinal fluid. Glucose results are used in the diagnosis and treatment of carbohydrate and metabolism disorders including diabetes mellitus, hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

The ATAC PAK Glucose Reagent determines glucose through the enzymatic action of hexokinase and glucose-6-phosphate dehydrogenase to produce to NADH. The resulting increase in absorbance at 340 nm is proportional to the glucose concentration in the sample.

The ATAC PAK Glucose Reagent Kit and ATAC Calibrator are substantially equivalent to the Beckman Synchron Glucose Reagent Kit, which is currently marketed by Beckman Coulter Inc. of Brea California.

The effectiveness of ATAC PAK Glucose Reagent Kit and the ATAC Calibrator used on the ATAC 8000 Random Access Chemistry System are shown by the following studies.

The recovery of glucose using the ATAC PAK Glucose Reagent is linear from 2 to 450 mg/dL or from 400 to 900 mg/dL as shown by the recovery of linearity standards which span the primary usable range and the hyperactive dilution range respectively. Regression statistics, which compare standard recoveries to standard values in both ranges, are shown below.

Primary Usable Range

(ATAC Recoveries) = 1.7 mg/dL + 0.980 x (Standard Value), $r^2 = 1.000$, $s_{y.x} = 3.8$ mg/dL, df = 49

Hyperactive Usable Range

(ATAC Recoveries) = 9.1 mg/dL + 0.935 x (Standard Value), $r^2 = 0.989$, $s_{y.x} = 19.5$ mg/dL, df = 49

Precision, using both the normal sample volume and the reduced sample volume with hyperactive dilution, is demonstrated by the replicate assay of commercially available serum and CSF controls and urine pools. Precision statistics, calculated analogous to the method described in NCCLS Guideline EP3-T, are shown below.

Precision of Glucose Recoveries in mg/dL

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	60	53	1.1	2.1%	1.4	2.7%
Serum 2	60	228	3.4	1.5%	4.6	2.0%
Serum 3	60	401	5.5	1.4%	8.9	2.2%
Urine 1	60	21	0.7	3.1%	1.0	4.7%
Urine 2	60	319	4.6	1.4%	6.9	2.2%
CSF 1	60	59	0.8	1.4%	1.4	2.4%
CSF 2	60	28	0.7	2.5%	0.9	3.2%

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Elan Diagnostics
is a division of Elan Pharmaceuticals

Precision of Glucose Recoveries in mg/dL using Hyperactive Dilution

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	60	496	12	2.4%	16	3.3%
Serum 2	60	626	10	1.7%	20	3.2%
Serum 3	59	768	18	2.3%	25	3.3%
Urine 1	60	560	9	1.6%	18	3.3%
Urine 2	60	868	14	1.7%	25	2.9%

Mixed serum and plasma, CSF and spiked urine specimens, collected from adult patients, were assayed for glucose using the ATAC 8000 Random Access Chemistry System and another commercially available method. Results were compared by least squares regression and the following statistics were obtained.

Serum/Plasma Comparison
(ATAC 8000) = 1.5 mg/dL + 1.010 x (Competitive Reagent)
r = 0.999 n = 196 range = 46 - 360 mg/dL

Urine Comparison
(ATAC 8000) = 1.2 mg/dL + 1.000 x (Competitive Reagent)
r = 0.998 n = 73 range = 15 - 392 mg/dL

CSF Comparison
(ATAC 8000) = 2.1 mg/dL + 0.982 x (Competitive Reagent)
r = 1.000 n = 40 range = 28 - 357 mg/dL

The detection limit claim of 2 mg/dL is documented through the repetitive assay of a diluted serum control. The observed detection limit, calculated as two standard deviations of a 30 replicate within run precision study, is 1.02 mg/dL and is below the claimed limit of 2 mg/dL.

The 30 day on board reagent stability and 14 day calibration stability claims are documented through the assay of serum and CSF controls and urine pools over the claimed periods. In all cases, the total imprecision of glucose recoveries over the test periods are less than 5 mg/dL or 5% for the primary usable range or less than 10% for the extended hyperactive dilution range.

Wynn Stocking
Manager of Regulatory Affairs
Elan Diagnostics

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 17 2000

Mr. Wynn Stocking
Manager, Regulatory Affairs
Elan Diagnostics
231 N. Puente Street
Brea, California 92821

Re: K000556
Trade Name: ATAC PAK Glucose Reagent and ATAC Calibrator
Regulatory Class: II
Product Code: CFR
Dated: February 16, 2000
Received: February 18, 2000

Dear Mr. Stocking:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K000556

Device Name: ATAC PAK Glucose Reagent and ATAC Calibrator

Indications For Use:

The ATAC PAK Glucose Reagent Kit, the ATAC Calibrator and the ATAC 8000 Random Access Chemistry System are intended for use as a system for the quantitative determination of glucose in serum, plasma, urine and cerebrospinal fluid. Glucose results are used in the diagnosis and treatment of carbohydrate and metabolism disorders including diabetes mellitus, hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

This reagent is intended to be used by trained personnel in a professional setting and is not intended for home use.

Respectfully,

Wynn Stocking

Wynn Stocking
Regulatory Affairs Manager
Elan Diagnostics

27 April, 2000

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000556

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)